

# Prednisone

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

Revision date:

Version: 1.0

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Chemical type : Substance  
Substance name : Prednisone  
  
EC no : 200-160-3  
CAS No. : 53-03-2  
Product code : 258954  
IUPAC name : 17,21-Dihydroxypregna-1,4-diene-3,11,20-trione  
Formula : C<sub>21</sub>H<sub>26</sub>O<sub>5</sub>

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### 1.2.1. Relevant identified uses

Main use category : Pharmaceutical  
Function or use category : Raw material

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

Duchefa FARMA BV  
A. Hofmanweg 71  
2031BH Haarlem - Netherlands  
T +31(0)23-5319093 - F +31(0)23-5318027  
[info@duchefa.com](mailto:info@duchefa.com) - [www.duchefa.com](http://www.duchefa.com)

#### 1.4. Emergency telephone number

Country	Official advisory body	Address	Emergency number
UNITED KINGDOM	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	0870 243 2241

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute Tox. 4 (Oral) H302  
Acute Tox. 4 (Dermal) H312  
Repr. 1B H360

Full text of H-phrases: see section 16

##### Classification according to Directive 67/548/EEC or 1999/45/EC

Repr.Cat.1; R61  
Repr.Cat.3; R62  
T; R23/24/25  
R48

Full text of R-phrases: see section 16

#### Adverse physicochemical, human health and environmental effects

No additional information available

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### 2.2. Label elements

#### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



GHS08

GHS07

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H302 - Harmful if swallowed  
H312 - Harmful in contact with skin  
H360 - May damage fertility or the unborn child

Precautionary statements (CLP)

: P202 - Do not handle until all safety precautions have been read and understood  
P281 - Use personal protective equipment as required  
P308+P313 - IF exposed or concerned: Get medical advice/attention

### 2.3. Other hazards

This substance/mixture does not meet the PBT/vPvB criteria of REACH, annex XIII.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Name	Product identifier	%	Classification according to Directive 67/548/EEC
Prednisone (Main constituent)	(CAS No.) 53-03-2 (EC no) 200-160-3	97 - 103	Repr.Cat.1; R61 Repr.Cat.3; R62 T; R23/24/25 R48

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Prednisone (Main constituent)	(CAS No.) 53-03-2 (EC no) 200-160-3	97 - 103	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Repr. 1B, H360

Full text of R-, H- and EUH-phrases: see section 16.

### 3.2. Mixtures

Not applicable

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures after inhalation	: Remove victim to fresh air. If not breathing, give artificial respiration. Seek medical advice.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Seek medical advice.
First-aid measures after eye contact	: Rinse immediately with plenty of water. Seek medical advice.
First-aid measures after ingestion	: Rinse mouth. Never give anything by mouth to an unconscious person. Seek medical attention immediately.

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries	: Exposure may produce an allergic reaction. May produce irregular heart beat and nervous symptoms. Gastrointestinal complaints. Risk of lungs oedema. Weakening of the immune system.
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Chronic symptoms : Based on animal experimentation, it is proved that product is or has showed teratogenic effects. May affect: . endocrine system.

### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media : All extinguishing agents can be used.

### 5.2. Special hazards arising from the substance or mixture

Fire hazard : On exposure to high temperature, may decompose, releasing toxic gases. Carbon monoxide.

Explosion hazard : Product is not explosive.

### 5.3. Advice for firefighters

Firefighting instructions : Avoid (reject) fire-fighting water to enter environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

Emergency procedures : Ensure adequate air ventilation. Avoid raising dust.

#### 6.1.2. For emergency responders

Protective equipment : Wear proper protective equipment. Wear respiratory protection.

### 6.2. Environmental precautions

Prevent product from entering drains.

### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up dry powder and dispose properly. To clean the floor and all objects contaminated by this material, use : Sodium hypochlorite solution.

### 6.4. Reference to other sections

No additional information available

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, well-ventilated area. Keep container tightly closed. Protect from sunlight.

Maximum storage period : 5 year

### 7.3. Specific end use(s)No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No additional information available

### 8.2. Exposure controls

Hand protection : Wear suitable gloves resistant to chemical penetration.

Eye protection : Safety glasses.

Skin and body protection : Wear suitable protective clothing.

Respiratory protection : Dust production: dust mask with filter type P3.

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### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 358,4 g/mol
Colour	: White.
Odour	: Odourless.
Odour threshold	: No data available
pH	: No data available
Melting point	: 233 °C
Solidification point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Flammability (solid, gas)	: No data available
Explosive limits	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Material nearly insoluble in water. Soluble in : Sodium hypochlorite solution.
Log Pow	: 1,46
Self ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available

#### 9.2. Other information

No additional information available

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

No additional information available

#### 10.2. Chemical stability

Stable under normal conditions.

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### 10.3. Possibility of hazardous reactions

No additional information available

### 10.4. Conditions to avoid

High temperature. Light (daylight).

### 10.5. Incompatible materials

Strong oxidizers.

### 10.6. Hazardous decomposition products

Carbon dioxide. Carbon monoxide.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Harmful if swallowed. Harmful in contact with skin.

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : May damage fertility or the unborn child.

Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : Not classified

Aspiration hazard : Not classified

## SECTION 12: Ecological information

### 12.1. Toxicity

#### Prednisone (53-03-2)

EC50 other aquatic organisms 1 31 mg/l Algae, 72h

### 12.2. Persistence and degradability

#### Prednisone (53-03-2)

Biodegradation

### 12.3. Bioaccumulative potential

#### Prednisone (53-03-2)

Log Pow 1,46

### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

#### Prednisone (53-03-2)

This substance/mixture does not meet the PBT/vPvB criteria of REACH, annex XIII.

### 12.6. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste treatment methods : Avoid release to the environment.

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

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### SECTION 14: Transport information

No dangerous good in sense of transport regulations.

### SECTION 15: Regulatory information

#### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

##### 15.1.1. EU-Regulations

No additional information available

##### 15.1.2. National regulations

No additional information available

#### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

### SECTION 16: Other information

Full text of R-, H- and EUH-phrases:		
	Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
	Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
	Repr. 1B	Reproductive toxicity Category 1B
	H302	Harmful if swallowed
	H312	Harmful in contact with skin
	H360	May damage fertility or the unborn child
	R23/24/25	Toxic by inhalation, in contact with skin and if swallowed.
	R48	Danger of serious damage to health by prolonged exposure.
	R61	May cause harm to the unborn child.
	R62	Possible risk of impaired fertility.
	T	Toxic

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*